IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO A.C.R.A.F. S.p.A.,	)	
Plaintiff,	)	
v.	)	C.A. No. 19-2197 (RGA)
AUROBINDO PHARMA USA INC.,	)	
Defendant.	)	

ANSWER AND COUNTERCLAIMS TO THE COMPLAINT

Aurobindo Pharma USA Inc. ("Aurobindo"), through its undersigned counsel, hereby answers the complaint filed by Plaintiff Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. ("Angelini" or "Plaintiff") and alleges in response to the numerous allegations set forth in the complaint of November 25, 2019, involving trazodone hydrochloride tablets (DESYREL®), as follows:

1. **This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing, made by Aurobindo Pharma USA Inc. ("Aurobindo"), of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial use or sale of a generic version of DESYREL® (trazodone hydrochloride) in tablet form in doses of 50, 100, 150, and 300 mg, before the expiration of U.S. Patent No. 8,133,893 ("the '893 patent"). The '893 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluation (the "Orange Book").**

ANSWER: Aurobindo admits that Plaintiff has brought an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. §100 et seq., and that Plaintiff has asserted that it arises from Aurobindo's Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of DESYREL® (trazodone hydrochloride) in tablet form in doses of 50, 100, 150, and 300 mg, but deny any remaining allegations of Paragraph 1 of the Complaint.

2. **DESYREL® is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder.**

ANSWER: Aurobindo directs Plaintiff to the labelling for DESYREL® for the best evidence as to the FDA-approved uses of trazodone hydrochloride oral tablets, but denies any remaining allegations of Paragraph 2.

3. **Aurobindo notified Plaintiff, by letter dated October 11, 2019 ("Aurobindo's Notice Letter") that it had submitted to the FDA ANDA No. 20-4852 ("Aurobindo's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic "trazodone hydrochloride oral tablet 50, 100, 150, and 300 mg" ("Aurobindo's ANDA Product") prior to the expiration of the '893 patent.**

ANSWER: Admitted.

4. **Plaintiff received Aurobindo's Notice Letter on October 15, 2019.**

ANSWER: Aurobindo lacks sufficient information to form a belief as to the allegations of Paragraph 4.

5. **Upon information and belief, Aurobindo's ANDA Product is a drug product that is a generic version of DESYREL®, containing the same or equivalent ingredients in the same or equivalent amounts, which Aurobindo claims is bioequivalent to DESYREL®.**

ANSWER: Aurobindo admits that Aurobindo's ANDA Product is a drug product that is a generic version of DESYREL®, containing the same active ingredient, but otherwise denies the remaining allegations of Paragraph 5.

6. **Upon information and belief, Aurobindo submitted its ANDA to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '893 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product.**

ANSWER: Admitted.

PARTIES

7. **Plaintiff Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. ("Angelini") is a company organized under the laws of Italy with its principal place of business at Viale Amelia 70, Rome 00181 Italy. Angelini is the assignee of the '893 patent.**

ANSWER: Upon information and belief, Aurobindo admits that Angelini is a company organized and existing under the laws of Italy and that it has a place of business at Viale Amelia 70, Rome 00181 Italy. Upon information and belief, based on USPTO assignment records and in accordance with the face of the '893 patent as annexed to Plaintiff's Complaint as Exhibit A, Angelini is the assignee of the '893 patent. Aurobindo denies the remaining allegations of Paragraph 7.

8. **Upon information and belief, defendant Aurobindo is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520-1401. Upon information and belief, Aurobindo is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.**

ANSWER: Aurobindo admits that it is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520-1401. Aurobindo admits that it is in the business of, among other things, manufacturing and selling generic pharmaceutical products in the United States. Aurobindo denies the remaining allegations of Paragraph 8.

JURISDICTION

9. **Jurisdiction is proper in this district pursuant to at least 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.**

ANSWER: Paragraph 9 sets forth legal conclusions for which no response is required. To the extent that an answer is required, and for the limited purposes of this action only, Aurobindo states that it will not contest subject matter jurisdiction of this Court, and except as so expressly admitted, deny the allegations of Paragraph 9.

10. **This Court has personal jurisdiction over Aurobindo. Aurobindo is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Aurobindo is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a**

registered agent for service of process in Delaware at Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. It therefore has consented to general jurisdiction in Delaware. In addition, upon information and belief, Aurobindo develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

ANSWER: Paragraph 10 sets forth legal conclusions for which no response is required. To the extent that an answer is required, Aurobindo admits that it is qualified to do business in Delaware, has appointed a registered agent for service of process in Delaware, and sells some of its generic products in Delaware. Aurobindo admits that it will not contest personal jurisdiction of this Court for the purposes of this action, and except as so expressly admitted, deny the allegations of Paragraph 10.

11. **Upon information and belief, Aurobindo intends that upon approval of Aurobindo's ANDA, Aurobindo will manufacture Aurobindo's ANDA Product and will directly or indirectly market, sell, and distribute Aurobindo's ANDA Product throughout the United States, including in Delaware.**

ANSWER: Aurobindo lacks sufficient information to respond to the allegations of Paragraph 11, as its ultimate intentions regarding the manufacture of a drug upon ANDA approval are subject to market conditions and regulatory issues, which vary over time. Aurobindo denies the remaining allegations of Paragraph 11.

12. **Aurobindo has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a**

certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

ANSWER: Paragraph 12 sets forth legal conclusions to which no response is required. To the extent that an answer may be required, Aurobindo admits that it has, in the past, filed paragraph IV certifications as detailed above, served notice letters on companies, and engaged in patent litigation arising from the process contemplated by the Hatch-Waxman Act. Aurobindo denies the remaining allegations of Paragraph 12.

13. **Upon information and belief, Aurobindo, with knowledge of the Hatch-Waxman Act process, directed Aurobindo's Notice Letter to, *inter alia,* Plaintiff, and alleged in Aurobindo's Notice Letter that the '893 patent is invalid and/or will not be infringed by the commercial manufacture, use or sale of the Aurobindo's ANDA Product. Upon information and belief, Aurobindo knowingly and deliberately challenged the '893 patent knowing that when it did so that it was triggering a forty-five day period for Plaintiff to bring an action for patent infringement under the Hatch-Waxman Act.**

ANSWER: Paragraph 13 sets forth legal conclusions to which no response is required. To the extent that an answer may be required, Aurobindo admits that it delivered Aurobindo's Notice Letter to Angelini, and included Aurobindo's Paragraph IV Certification stating that the '893 patent is invalid and/or will not be infringed by the commercial manufacture, use or sale of Aurobindo's ANDA Product. Aurobindo denies the remaining allegations of Paragraph 13.

14. **Aurobindo has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Aurobindo's Notice Letter to Plaintiff, that it would be sued in Delaware for patent infringement.**

ANSWER: Paragraph 14 sets forth legal conclusions to which no response is required. To the extent that an answer may be required, Aurobindo admits that has been a Hatch-Waxman litigant in other cases. Aurobindo denies the remaining allegations of Paragraph 14.

15. **This Court, therefore, also has personal jurisdiction over Aurobindo because Aurobindo regularly engages in patent litigation concerning FDA-approved branded drug products in this district, does not contest personal jurisdiction in this district, and has availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Millennium Pharmaceuticals, Inc. v. Aurobindo Pharma USA Inc. et al.*, No. 1:19-cv- 00471- CFC (D. Del. 2019); *Genentech, Inc. et al. v. Aurobindo Pharma USA Inc. et al.*, No. 1:19-cv- 00105-RGA (D. Del. 2019); *Allergan Sales, LLC et al. v. Aurobindo Pharma USA, Inc. et al.*, No. 1:18-cv-001180-GMS (D. Del. 2018); *Kissei Pharmaceutical Co. Ltd. et al. v. Aurobindo Pharma USA Inc. et al.*, No. 1:17-cv-01161-LPS (D. Del. 2017).**

ANSWER: Paragraph 15 sets forth legal conclusions to which no response is required. To the extent that an answer may be required, Aurobindo admits that it has been involved in litigation in the District of Delaware before, and although Aurobindo does not admit that personal jurisdiction is proper, Aurobindo will not contest personal jurisdiction of this Court for the limited purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 15.

16. **Upon information and belief, if Aurobindo's ANDA is approved, Aurobindo will directly or indirectly manufacture, market, sell, and/or distribute Aurobindo's ANDA Product within the United States, including in Delaware, consistent with Aurobindo's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Aurobindo regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Aurobindo's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Aurobindo's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of the '893 patent in the event that Aurobindo's ANDA is approved before the patent expires.**

ANSWER: Paragraph 16 sets forth legal conclusions to which no response is required. To the extent that an answer may be required, Aurobindo admits that it has done and is doing business in Delaware, and sells drug products in various states of the United States, including in Delaware. Aurobindo denies that the decision to manufacture, market, sell, and/or distribute Aurobindo's ANDA Product within the United States would constitute infringement of the '893 patent. Aurobindo lacks sufficient information to respond to the remaining allegations of Paragraph 16, as the manufacture, marketing, sale, and/or distribution of a drug upon ANDA approval is subject to market variability over time. Aurobindo denies the remaining allegations of Paragraph 16.

17. **Upon information and belief, Aurobindo derives substantial revenue from pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Aurobindo and/or for which Aurobindo is the named applicant on approved ANDAs. Upon information and belief, various products for which Aurobindo is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.**

ANSWER: Paragraph 17 sets forth legal conclusions to which no response is required. To the extent that an answer may be required, Aurobindo admits that it derives a portion of its revenue from pharmaceutical products, among other things, and that certain Aurobindo products are available at retail pharmacies in Delaware. Aurobindo denies the remaining allegations of Paragraph 17.

18. **For the foregoing reasons, this Court has personal jurisdiction over Aurobindo.**

ANSWER: Aurobindo hereby reaffirms its responses to the foregoing reasons detailed in Paragraphs 9-17 of the Complaint. Aurobindo reaffirms that it does not admit that personal jurisdiction is proper, but that, for the limited purposes of this action only, Aurobindo will not contest personal jurisdiction of this Court.

VENUE

19. **Venue is proper in this district for Aurobindo pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* as a corporation organized and existing under the laws of the State of Delaware, Aurobindo is deemed to reside in this judicial district, and is subject to personal jurisdiction in this judicial district.**

ANSWER: Aurobindo admits that, for the limited purposes of this action only, it will not contest venue in this Court. Aurobindo denies the remaining allegations of Paragraph 19.

THE '893 PATENT

20. **The inventors named on the '893 patent are Marcello Marchetti, Tommaso Iacoangeli, Giovanni Battista Ciottoli and Giuseppe Biondi (collectively, "the Named Inventors").**

ANSWER: Paragraph 20 sets forth legal conclusions based on alleged activities to which no response is required. To the extent that an answer may be required, according to the face of the '893 patent as annexed to Plaintiff's Complaint as Exhibit A, Aurobindo admits that certain persons are named as inventors on the face of the '893 patent. Aurobindo lacks sufficient information to form a belief as to the truth of the remaining allegations of Paragraph 20, and therefore denies them.

21. **The '893 patent, entitled "Trazodone and Trazodone Hydrochloride in Purified Form," was duly and legally issued on March 12, 2012, to Angelini as assignee of the Named Inventors. A copy of the '893 patent is attached as EXHIBIT A.**

ANSWER: Paragraph 21 sets forth legal conclusions based on alleged activities to which no response is required. To the extent that an Answer may be required, according to the face of the '893 patent as annexed to Plaintiff's Complaint as Exhibit A, Aurobindo admits that the '893 patent is entitled "Trazodone and trazodone hydrochloride in purified form," was issued on March 13, 2012, and lists Angelini as assignee of the Named Inventors. Aurobindo lacks sufficient information to form a belief as to the truth of the remaining allegations of Paragraph 21, and therefore denies them.

22. **The '893 patent claims, *inter alia*, trazodone or trazodone hydrochloride comprising less than 15 parts per million of alkylating substances, a pharmaceutical composition of trazodone hydrochloride, and a process of production of trazodone or trazodone hydrochloride.**

ANSWER: Paragraph 22 sets forth legal conclusions based on alleged activities to which no response is required. In particular, the interpretation of the claims as to what they cover is a legal matter for which no response is required. Aurobindo lacks sufficient information to form a belief as to the truth of the remaining allegations of Paragraph 22, and therefore denies them.

23. **Angelini is assignee of the '893 patent, and has the right to enforce the '893 patent.**

ANSWER: Paragraph 23 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer may be required, Aurobindo admits that Plaintiff is listed in the USPTO assignment records as assignee of the '893 patent. Aurobindo lacks sufficient information to form a belief as to the truth of the remaining allegations of Paragraph 22, and therefore denies them.

24. **DESYREL®, and methods of producing DESYREL®, are covered by one or more claims of the '893 patent.**

ANSWER: Paragraph 24 sets forth legal conclusions based on alleged activities to which no response is required. In particular, the interpretation of the claims as to what they cover is a legal matter for which no response is required. Aurobindo lacks sufficient information to form a belief as to the truth of the remaining allegations of Paragraph 24, and therefore denies them.

25. **The '893 patent has been listed in connection with DESYREL® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."**

ANSWER: Admitted.

26. **Plaintiff will be substantially and irreparably damaged by infringement of the '893 patent because Angelini is the exclusive supplier of the active pharmaceutical ingredient in DESYREL®.**

ANSWER: Aurobindo denies the allegations of Paragraph 26.

COUNT I - AUROBINDO'S INFRINGEMENT OF THE '893 PATENT

27. **Plaintiff incorporates each of the preceding paragraphs 1-26 as if fully set forth herein.**

ANSWER: Aurobindo repeats, restates and reaffirms each of its responses to the preceding Paragraphs 1-26 as if fully set forth at length herein.

I. **Direct Infringement**

28. **In Aurobindo's Notice Letter, Aurobindo notified Plaintiff that it had submitted Aurobindo's ANDA to the FDA. The purpose of the submission of the ANDA was to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product in the United States prior to the expiration of the patent-in-suit.**

ANSWER: Paragraph 28 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits the contents

of its Notice Letter to plaintiffs and directs Plaintiffs to the same. Aurobindo denies the remaining allegations of Paragraph 28.

29. **In its Notice Letter, Aurobindo also notified Plaintiff that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '893 patent.**

ANSWER: Admitted.

30. **Aurobindo's ANDA is an application for a drug claimed in one or more claims of the '893 patent, including at least claim 1.**

ANSWER: Paragraph 30 sets forth legal conclusions based on alleged activities to which no response is required. To the extent that an answer may be required, Aurobindo denies the allegations of Paragraph 30.

31. **Aurobindo has knowledge of the ' 893 patent.**

ANSWER: Admitted.

32. **Aurobindo's submission of its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product in the United States before the expiration of the '893 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).**

ANSWER: Denied.

33. **Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Product in the United States immediately and imminently upon approval of its ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.**

ANSWER: Aurobindo again states that it lacks sufficient information to respond to the claims of Paragraph 33, as the decision to manufacture, use, offer for sale, sell, market, distribute, and/or import any pharmaceutical product is subject to numerous unknown factors that may influence Aurobindo's decision upon approval of its ANDA. Aurobindo therefore denies the allegations of Paragraph 33.

34. **The manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product in the United States would infringe one or more claims of the '893 patent, including at least claim 1.**

ANSWER: Denied.

35. **Upon information and belief, the manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product in the United States in accordance with, and as directed by Aurobindo's proposed product labeling would infringe one or more claims of the '893 patent, including at least claim 1.**

ANSWER: Denied.

II. **Indirect Infringement: Contributory Infringement**

36. **Upon information and belief, for at least the following reasons, Aurobindo plans and intends to, and will, actively indirectly infringe the '893 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.**

ANSWER: Denied.

37. **Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '893 patent, that Aurobindo's ANDA Product is not a staple article or commodity of**

commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '893 patent immediately and imminently upon approval of Aurobindo's ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.

ANSWER: Denied.

38. **Notwithstanding Aurobindo's knowledge of the claims of the '893 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling upon FDA approval of Aurobindo's ANDA and prior to the expiration of the '893 patent.**

ANSWER: Paragraph 38 sets forth legal conclusions to which no response is required. To the extent that an answer may be required, Aurobindo admits that it continues to pursue approval from the FDA of Aurobindo's ANDA Product. To the extent that any allegations remain, Aurobindo denies them.

III. **Indirect Infringement: Inducement of Infringement**

39. **Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product will induce the direct infringement of the '893 patent by a number of direct infringers, including, but not limited to Aurobindo's customers, distributors, affiliates, employees and manufacturers. Upon information and belief, Aurobindo plans and intends to, and will, induce others to directly infringe the '893 patent immediately and imminently upon approval of Aurobindo's ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.**

ANSWER: Denied.

40. **Notwithstanding Aurobindo's knowledge of the claims of the '893 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product in the United States with its product labeling upon FDA approval of Aurobindo's ANDA and prior to the expiration of the '893 patent, with the knowledge that such activities will induce direct infringement of the '893 patent by others.**

ANSWER: Paragraph 40 sets forth legal conclusions to which no response is required. To the extent that an answer may be required, Aurobindo admits that it continues to pursue approval from the FDA of Aurobindo's ANDA Product. To the extent that any allegations remain, Aurobindo denies them.

41. **The foregoing actions by Aurobindo, with Aurobindo's knowledge detailed above, constitute and/or will constitute infringement of the '893 patent; active inducement of infringement of the '893 patent; and/or contribution to the infringement by others of the '893 patent.**

ANSWER: Denied.

42. **Upon information and belief, Aurobindo has acted with full knowledge of the '893 patent and without a reasonable basis for believing that it would not be liable for infringement of the '893 patent; active inducement of infringement of the '893 patent; and/or contribution to the infringement by others of the '893 patent.**

ANSWER: Denied.

43. **Unless Aurobindo is enjoined from infringing the '893 patent, actively inducing infringement of the '893 patent, and contributing to the infringement by others of the '893 patent, Plaintiff will suffer irreparable injury because Plaintiff is the exclusive**

supplier of the active pharmaceutical ingredient covered by the '893 patent. Plaintiff has no adequate remedy at law.

ANSWER: Denied.

COUNT II - DECLARATORY JUDGMENT OF INFRINGEMENT BY AUROBINDO OF THE '893 PATENT

44. **Plaintiff incorporates paragraphs 1-43 as if fully set forth herein.**

ANSWER: Aurobindo repeats, restates and reaffirms each of the its responses to the preceding Paragraphs 1-43 as if fully set forth at length herein.

45. **The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, and contribution to the infringement by others of the '893 patent.**

ANSWER: Paragraph 45 sets forth legal conclusions based on alleged activities to which no response is required. To the extent that an answer may be required, Aurobindo denies these allegations.

46. **The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Aurobindo's ANDA Product, or any other drug product which is covered by, or use of which is covered by one or more claims of the '893 patent, will infringe, induce the infringement of, or contribute to the infringement by others of, that patent.**

ANSWER: Denied.

47. **Plaintiff will be irreparably harmed by the sale of Aurobindo's ANDA Product because Plaintiff is the exclusive supplier to third parties that sell or plan to sell pharmaceutical drugs containing of the active pharmaceutical ingredient covered by the '893 patent.**

ANSWER: Denied.

PLAINTIFF'S PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

(a) **A judgment that each claim of the '893 patent has been infringed under 35 U.S.C. § 271(e)(2) by Aurobindo's submission to the FDA of Aurobindo's ANDA;**

(b) **A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Aurobindo's ANDA Product, or any other drug product that infringes or the use of which infringes one or more claims of the '893 patent, be not earlier than the latest of the expiration dates of the '893 patent, inclusive of any extension(s) and additional period(s) of exclusivity;**

(c) **A preliminary and permanent injunction enjoining Aurobindo, and all persons acting in concert with Aurobindo, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product, or any other drug product covered by or whose use is covered by one or more of the claims of the '893 patent, prior to the expiration of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;**

(d) **A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product, or any other drug product which is**

covered by or whose use is covered by one or more of the claims of the '893 patent, prior to its expiration, will infringe, induce the infringement of, and contribute to the infringement by others of, the '893 patent;

(e) **A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;**

(f) **Costs and expenses in this action; and**

(g) **Such further and other relief as this Court may deem just and proper.**

ANSWER TO PLAINTIFF'S PRAYER FOR RELIEF: The "WHEREFORE" paragraphs following Paragraph 47 states Plaintiff's prayer for relief for which no response is required. To the extent a response is required, Aurobindo denies the allegations contained in the "WHEREFORE" paragraphs following Paragraph 46 of the Complaint and denies that Plaintiff is entitled to any of the relief required, or to any relief whatsoever. Aurobindo specifically denies that Plaintiff is entitled to the general or specific relief requested against Aurobindo, or to any relief whatsoever, and pray for judgment in favor of Aurobindo dismissing this action with prejudice, and awarding Aurobindo its reasonable attorneys' fees.

AFFIRMATIVE DEFENSES

Aurobindo asserts the following defenses without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE (FAILURE TO STATE A CLAIM)

Plaintiffs' Complaint, in whole or in part, fails to state claims upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE
(INVALIDITY AND UNENFORCEABILITY)

United States Patent No. 8,133,893 ("the '893 patent") (the "Patent-In-Suit") and each of the claims thereof, are invalid and/or unenforceable for failure to comply with one or more conditions for patentability and/or enforceability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidity and/or unenforceability, as more particularly set for in the Notice Letter ("Aurobindo's Notice Letter") sent in respect Aurobindo's Paragraph IV Certifications ("Aurobindo's Paragraph IV Certification").

THIRD AFFIRMATIVE DEFENSE
(NO DIRECT INFRINGEMENT)

As detailed in in the Detailed Statement of the Aurobindo's Notice Letter, Aurobindo does not infringe literally any valid and enforceable claim of the Patent-In-Suit and thus cannot be said to literally infringe the same. As no equivalent can be found in Defendant's proposed product for the missing elements of any of the claims of the Patent-In-Suit, there can be no be no infringement under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE
(NO INDIRECT INFRINGEMENT)

Defendant has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patent-In-Suit, and the manufacturing, marketing, sale, offer for sale, importation, and/or distribution of the Aurobindo ANDA product does not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patent-In-Suit.

FIFTH AFFIRMATIVE DEFENSE (NO COSTS)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

SIXTH AFFIRMATIVE DEFENSE (FAILURE TO STATE CLAIM OF WILFULNESS)

Plaintiffs fail to state a proper claim for willful infringement or exceptional case under 35 §§ 271(e)(4) and 285, or otherwise.

SEVENTH AFFIRMATIVE DEFENSE (RESERVATION OF RIGHTS)

Defendant reserves the right to assert additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS OF AUROBINDO

Pursuant to Rule 13 of the Federal Rules of Civil Procedure Aurobindo Pharma USA Inc., ("Aurobindo" or "Counterclaim-Plaintiff"), through its undersigned attorneys, for its Counterclaims against Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. ("Angelini" or "Counterclaim-Defendant") hereby states the following:

1. Counterclaim-Plaintiff repeats and incorporates by reference each of the foregoing paragraphs of Aurobindo's (Defendant's) Answer and Affirmative Defenses to the Complaint.

2. This is an action for a declaratory judgment of non-infringement and invalidity of the claims of United States Patent No. 8,133,893 ("the '893 patent") (the "Patent-In-Suit"). Upon information and belief, a true and correct copy of the Patent-In-Suit is attached to the Complaint as Exhibit A.

THE PARTIES

3. Counterclaim-Plaintiff Aurobindo Pharma USA Inc. is a corporation organized and

existing under the laws of Delaware, having a place of business at 279 Princeton-Hightstown Rd., East Windsor, NJ 08520-1401 USA.

4. On information and belief, based on the complaint filed by Plaintiff /Counterclaim-Defendant in this case, Angelini is a company organized under the laws of Italy with its principal place of business at Viale Amelia 70, Rome 00181 Italy.

JURISDICTION

5. This court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U .S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Counterclaim-Plaintiff, on the one hand, and the Counterclaim-Defendant on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

6. This court has personal jurisdiction over Counterclaim Defendants based, *inter alia*, on the filing by Counterclaim-Defendant of this lawsuit in this jurisdiction and because Counterclaim-Defendants are doing business in this jurisdiction.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

ORANGE BOOK LISTING OF THE PATENT

8. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holder believes claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

9. On information and belief, on March 13, 2012, the U.S. Patent and Trademark Office ("PTO") issued the '893 patent. On information and belief, a true and correct copy of the

'893 patent is attached to the complaint as Exhibit A.

10. On information and belief, pursuant to 21 U.S.C. §§ 355(b)(l), Counterclaim-Defendant caused the FDA to list the Patent-In-Suit in the Orange Book in connection with NDA No. 18-207 in respect of the brand name product DESYREL® (generic name Trazodone Hydrochloride) ("DESYREL® NDA").

11. By maintaining the listings of the Patent-in-Suit in the Orange Book, Counterclaim-Defendant represents to the world that the Patent-In-Suit could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale (21 U.S.C. § 355(b)(l)) of the respective brand name product before the expiration of the Patent-in-Suit.

AUROBINDO'S ABBREVIATED NEW DRUG APPLICATION

12. Aurobindo filed ANDA No. 20-4852 ("Aurobindo's ANDA") with the FDA seeking approval to market generic trazodone hydrochloride tablets, intended to be a generic version of DESYREL®. Aurobindo's ANDA included a Paragraph IV Certification to the Patent-in-Suit, certifying that to the best of its knowledge that all of the claims of the Patent-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, and/or importation of the product described in Aurobindo's ANDA.

THE PRESENCE OF A CASE OF CONTROVERSY

13. By maintaining the Orange Book listing of the Patent-in-Suit in connection with DESYREL®, Counterclaim-Defendant represents that the Patent-in-Suit could reasonably be asserted against anyone making, using or selling generic trazodone hydrochloride tablets, intended to be generic version of DESYREL®, without a license from the Counterclaim-Defendant prior to the expiration of the Patent-in-Suit.

14. Counterclaim-Defendant has filed an infringement action under Title 35, United

States Code, Sections 100 et seq., asserting the Patent-In-Suit against Counterclaim-Plaintiff and seeking a declaration of infringement regarding the Patent-In-Suit. There has been, and is now, an actual and justiciable controversy between Counterclaim-Plaintiff on the one hand, and Counterclaim-Defendant, on the other hand, as to whether the products disclosed in Aurobindo's ANDA infringe the Patent-in-Suit, and whether any valid, enforceable claim in the Patent-in-Suit exists.

15. Aurobindo seeks to market generic trazodone hydrochloride tablets that are the subject of Aurobindo's ANDA in the United States prior to the expiration of the Patent-In-Suit.

16. If Counterclaim-Plaintiff succeeds in proving that its generic trazodone hydrochloride tablets that are the subject of Aurobindo's ANDA do not infringe the Patent-in-Suit or claims are invalid or unenforceable, and thus non-infringing, such a judgment will remove any uncertainty that may exist by virtue of Counterclaim-Defendant's maintenance of the Patent-In-Suit in the Orange Book in connection with the DESYREL® NDA.

17. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaim-Defendant and Counterclaim-Plaintiff as to whether the claims of the Patent-in-Suit are invalid and/or not infringed by Counterclaim-Plaintiff.

COUNT I

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE PATENT-IN-SUIT)

18. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-17 of their Counterclaims, above, as if fully set forth herein.

19. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual,

substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiff and Counterclaim-Defendant concerning the Patent-in-Suit and the claims of the Patent-in-Suit.

20. Counterclaim-Defendant alleges that the commercial manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiff's generic trazodone hydrochloride tablets that are the subject of Aurobindo's ANDA infringes one or more claims of the Patent-In-Suit.

21. Counterclaim-Plaintiff asserts that no valid claim of the Patent-in-Suit is infringed by the manufacture, use, offer for sale, sale, and/or importation of generic trazodone hydrochloride tablets that are the subject of Aurobindo's ANDA.

22. Counterclaim-Plaintiff is entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiff's generic trazodone hydrochloride tablets that are the subject of Aurobindo's ANDA, do not infringe any valid claim of the Patent-in-Suit.

COUNT II

(DECLARATORY JUDGMENT OF INVALIDITY OF THE PATENT-IN-SUIT)

23. Counterclaim-Plaintiff repeats and incorporates by reference Paragraphs 1-22 of Counterclaim-Plaintiff's Counterclaims, above, as if fully set forth herein.

24. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiff and Counterclaim-Defendant concerning the claims of the Patent-in-Suit.

25. Counterclaim Defendant alleges that the commercial manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiff's generic trazodone hydrochloride tablets that are the subject of Aurobindo's ANDA, infringes one or more claims of the Patent-in-Suit.

26. Counterclaim-Plaintiff asserts that the manufacture, use, offer-for-sale, sale, and/or importation of Counterclaim-Plaintiff's generic trazodone hydrochloride tablets that are the subject of Aurobindo's ANDA do not infringe any valid claim of the Patent-in-Suit, and that the claims of the Patent-in-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation.

27. Counterclaim-Plaintiff is entitled to a declaration that the claims of the Patent-in-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff respectfully requests that the Court enter judgment in its favor and against Counterclaim-Defendant as follows:

a. Denying Counterclaim-Defendant's claims and dismissing Plaintiff's Complaint with prejudice.

b. For a declaration that the claims of the Patent-in-Suit are invalid;

c. For a declaration that the claims of the Patent-in-Suit are not, and will not be, infringed by Counterclaim-Plaintiff's manufacture, use, sale, offer for sale, or importation of the generic trazodone hydrochloride tablets that is the subject of Aurobindo's ANDA;

d. Preliminarily and permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from utilizing the Patent-in-Suit to block, hamper, hinder or obstruct

FDA approval of Counterclaim-Plaintiff's proposed product;

e. Permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from asserting or otherwise seeking to enforce the Patent-in-Suit against Counterclaim-Plaintiff or anyone in privity with Counterclaim-Plaintiff;

f. Declaring this case exceptional and awarding Counterclaim-Plaintiff its attorneys' fees pursuant to 35 U.S.C. § 285, the inherent power of this Court, or otherwise;

g. Awarding costs to Counterclaim-Plaintiff; and

h. Awarding to Counterclaim-Plaintiff any other such and further relief as is just and proper.

Dated: February 3, 2020

Respectfully submitted,

/s/ Kenneth L. Dorsney

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